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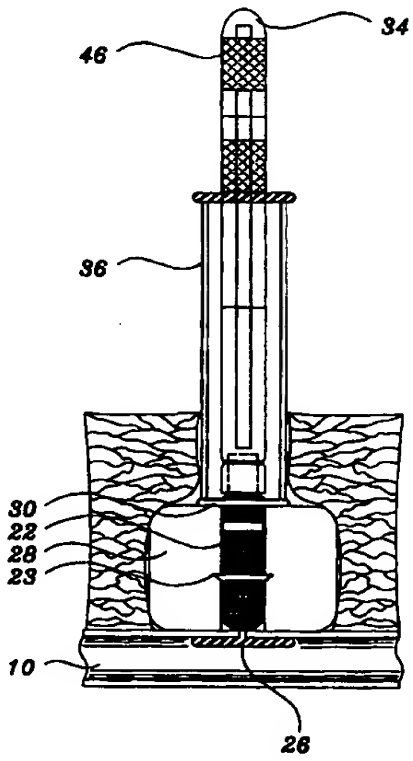
(54) Title: BIOABSORBABLE HEMOSTATIC SEALING ASSEMBLY

(57) Abstract

This invention is a device (18) and method of closing an incision or puncture in a patient by inserting a closure device into the incision or puncture until the anchor member of the closure device is along the wall of the blood vessel (10), or target organ adjacent to the puncture so that the closure device does not significantly obstruct the flow of fluid through the blood vessel or target organ, and then positioning a collagen member (28) along the outer surface of the blood vessel or target organ. The precise positioning of the closure device in the incision or puncture is accomplished through the use of an anchor member (26) which is preferably integral with a rod member (22) wherein the anchor member is adapted to be positioned along the inner wall of the blood vessel or target organ of the patient, and the rod member extends through the puncture and receives the expandable collagen member thereon.



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BIOABSORBABLE HEMOSTATIC SEALING ASSEMBLY

FIELD OF THE INVENTION

The present invention relates generally to closure devices and more particularly to an improved sealing assembly and closure device which are insertable into an incision or puncture formed in the body of a patient to seal the incision or puncture from the flow of body fluids therethrough.

BACKGROUND OF THE INVENTION

During catheterization or other medical procedures, a physician will create an opening into an artery, vessel or organ of a patient with a conventional needle, catheter, introducer or dilator. The size of the opening will vary depending on the type of procedure and the size of the catheter which is to be used. For example, the diameter of the catheter and catheter sheath used in standard angiography procedures is typically between 5 to 8 French (1.67 mm and 2.67 mm, respectively). The diameter of the catheter and catheter sheath used in angioplasty procedures and an increasing number of stent placement procedures may be about 8 (2.67 mm) or 9 (3.33 mm) French. The diameter of the catheter and catheter sheath used in intro-aortic balloon pump procedures is typically between 14 to 16 French (4.67 mm and 5.33 mm, respectively) and the diameter of the catheter and catheter sheath used with cardiopulmonary support systems is typically between 18 and 20 French (6.0 mm and 6.67 mm, respectively). Additionally, the catheter may often be twisted or otherwise manipulated as it is advanced to the treatment site, thereby causing a further enlargement of the incision or puncture in the body of the patient.

When the medical procedure is completed and the catheter is removed from the artery or other blood vessel, the conventional practice has been to apply external pressure to the entry site until clotting occurs. Because many of the patients undergoing these procedures have been medicated with an anticoagulant such as heparin, the nurse may be required to apply external pressure to the incision site for an extended period of time. The time required to stop bleeding at the incision is not an efficient use of the nurses time and a painful hematoma or unsightly bruise may still occur at the incision site because the artery will continue to bleed internally until clotting blocks the opening in the artery.

U.S. Patent No. 4,829,994 granted to Kurth on May 16, 1989, attempts to resolve the above-described problem by providing an apron-like device consisting of a pelvic apron and a groin strap to apply a compressive force to the femoral vessel of the patient. Although this device effectively eliminates the need to have a nurse apply direct pressure to the incision site, a decrease in blood flow through the femoral artery may be caused by the use of this device and may increase the likelihood of clot formation in the compromised patient.

Another approach to resolving the above-identified problem is disclosed in U.S. Patent No. 4,929,246 granted to Sinofsky on May 29, 1990. The method of using the device disclosed in this patent includes the steps of advancing a semi-rigid tube having an inflatable balloon at its distal end through the overlying tissue to a location adjacent to the outer wall of the punctured artery. The balloon is then inflated to apply pressure directly to the outer wall of the artery. Laser energy is then directed to the outer wall of the artery via an optical fiber centrally located in the semi-rigid tube such that the laser energy passes through the optical fiber and balloon of the semi-rigid tube to thermally weld the artery and seal the incision.

A further approach to resolving the above-identified problem is disclosed in U.S. Patent No. 4,744,364 granted to Kensey on May 17, 1988, and related U.S. Patent Nos. 4,852,568 and 4,890,612 granted to Kensey on August 1, 1989, and January 2, 1990, respectively. The first two Kensey patents disclose a device for sealing an opening in the wall of a blood vessel which consists of an elongate tubular body having an anchor member removably disposed therein. The tubular body also includes an ejecting device disposed within the tubular body for forcing the anchor member from the tubular body into the interior of the blood vessel. A retraction suture is secured to the anchor member so that the engagement surface of the anchor member hemostatically engages the inner surface of the blood vessel contiguous with the puncture. The '612 Kensey patent discloses a device which includes an elongate member having a portion thereof which is adapted to engage portions of the tissue adjacent to the punctured vessel and a sealing portion which extends through the incision to engage the tissue contiguous therewith to seal the puncture. Subsequent patents granted to Kensey et al. are illustrative of improvements to the basic approach described above and generally include an anchor member which is used in combination with a suture and a collagen member to seal an incision and blood vessel.

U.S. Patent No. 5,411,520 granted to Nash et. al. is illustrative of an improvement to the basic approach described above and generally includes a spacer which is movable along a suture to position the spacer between the anchor member and the collagen member to seal the puncture and blood vessel. The spacer is positioned between the collagen member and the anchor to prevent the collagen member from being entering the blood vessel of the patient.

U.S. Patent No. 5,108,421 granted to Fowler and assigned to the assignee of the present invention discloses the use of a "vessel plug" type approach wherein the hemostatic closure device is inserted into the incision of

the patient and may be positioned in the incision using a locating member such as an elongate balloon type member or a syringe type device. U.S. Patent No. 5,391,183 granted to Janzen et al. discloses another vessel plug type approach wherein one or more oversized vessel plugs are inserted into the incision using a device with a plunger member.

From the foregoing, it is apparent that while significant efforts have recently been directed to the development of a simple and relatively inexpensive means for reliably effecting the closure of a puncture or incision in the wall of a blood vessel, duct or organ to significantly reduce the time to ambulation of a patient as well as to reduce the risk of hematoma or clot formation further efforts are needed to satisfy these goals.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a device and method of use which overcomes the disadvantages of the prior art relating to simplicity of construction, ease of deployment, operation and/or safety of a vessel closure device.

It is another object of the present invention to reduce the time required for sealing an incision in an artery and to decrease the likelihood that a hematoma will form after the catheter is removed from the incision.

These and other objects of the present invention are achieved by providing a device and method for sealing an incision in a blood vessel, duct or organ using the device as described hereinafter.

One form of the present invention preferably includes a sealing assembly consisting of a vessel closure device including an elongate bioabsorbable rod member having an anchor member on the distal end thereof. The anchor member is preferably prestressed to extend laterally from the

distal end of the rod member after insertion while being sufficiently flexible to be aligned with the lengthwise dimension of the rod member during insertion of the closure device into the incision. The rod member also preferably includes a collagen tube extending along a portion thereof, locking groove and a retainment ring which is slidable lengthwise along the rod member.

In use, the sealing assembly includes a delivery which includes an introducer or procedure sheath, an extension rod and a push rod and a closure device which includes a bioabsorbable rod member, an anchor member and a retainment ring. The delivery device is initially positioned in the puncture so that the distal end of the introducer is positioned in the blood vessel of the patient and the closure device is positioned in and through the puncture. The distal end of the closure device is then pushed beyond the distal end of the introducer and the anchor member is allowed to move from a first position which is generally parallel to the lengthwise dimension of the rod member to a second position which is generally perpendicular to the lengthwise dimension of the rod member. The introducer and the closure device are then withdrawn together until the anchor member contacts and engages the wall of the blood vessel adjacent to the incision. Withdrawal of the introducer is then continued to expose the rod member and collagen member of the sealing device to the fluids in the incision. Next, the cylindrical extension rod of the delivery device is moved distally along the rod member sealing device to push a retainment ring distally along the rod member until the retainment ring reaches a locking point or locking groove on the rod member. The distal movement of the retainment ring along the rod member causes the compression and distal movement of the collagen tube along the rod member so that the collagen tube expands radially and is moved to a location generally adjacent to and proximally of the wall of the blood vessel.

The collagen tube of the closure device includes a distal end which is preferably sized and slightly blunt shaped so that the distal end of the collagen tube is reliably positioned proximally of the outer surface of the blood vessel and extends generally along the distal portion of the incision or puncture so that the collagen tube will not enter into the blood vessel. Additionally, the wall of the blood vessel is sandwiched between the anchor member and collagen tube. One function of the anchor member is to allow for the convenient and reliable positioning of the rod member and collagen tube in the incision or puncture and therefore, the size and shape of the anchor member is chosen to minimize any disruption in the flow of fluid past the incision and to be absorbed in the body of the patient within a relatively short period of time.

An advantage of the present invention is that the closure device does not include a suture member and the closure device functions essentially as a one piece sealing device.

Another advantage of the present invention is that anchor member and introducer of the present invention may be used to reliably position closure device generally along the wall of the blood vessel without significantly obstructing the blood vessel, duct or organ of the patient.

Another advantage of the present invention is that closure device of the present invention may be used to reliably position closure device generally along the wall of the blood vessel without being significantly affected by the depth of the puncture in the patient.

Yet another advantage of the present invention is that sealing device of the present invention may be readily modified to reliably position closure device generally along the wall of the blood vessel in nearly any diameter puncture without adversely affecting the operation of the device.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view, partially in cross section, showing the closure device and extension rod of the present invention;

Figure 2 is a partial side view showing the access sheath and bypass member of the present invention;

Figure 3 is a partial side view, partially in cross section, showing a front view of the anchor member of the closure device positioned in the access sheath;

Figure 4 is an enlarged partial side view of the folded anchor member in the access sheath;

Figure 5 is a side view, partially in cross section, showing the closing device and access sheath in the puncture tract with the anchor member of the closure device extended from the access sheath;

Figure 6 is a side view, partially in cross section, showing the sealing assembly of the present invention with the anchor member extended and positioned along the inner wall of the patient's blood vessel;

Figure 7 is a side view, partially in cross section, showing the closure device and extension rod of Figure 1 after the access sheath has been removed from the patient and having the closure device initially positioned in the incision;

Figure 8 is a side view, partially in cross section, showing the push rod installed on the extension rod and closure device;

Figure 9 is a side view, partially in cross section, showing the closure device and extension rod of Figure 1 in the incision after the push rod and retainment ring have been moved distally along the rod member to cause the radial expansion and distal movement of the collagen tube along the rod member;

Figure 10 is a side view, partially in cross section, showing the closure device of Figure 1 finally positioned

in the puncture tract after the proximal portion of the rod member has been removed;

Figure 11 is a side view showing the extension rod of Figure 1;

Figure 12 is a side view showing the push rod of the present invention;

Figure 13 is a side view showing the closure device of the present invention;

Figures 14A, 14B and 14C are front, side and bottom views respectively showing an alternate form of the retainment ring of Figure 1; and

Figure 15 is a side elevational view, partially in cross section, showing the alternate form of the retainment ring of Figure 14 showing the closure device finally positioned in the puncture tract.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

The present invention is described hereinafter with specific reference to the use of the present invention for sealing an incision or puncture in a blood vessel such as the femoral artery 10 of a patient. The sealing assembly 16 has particular utility when used in connection with intravascular procedures, such as angiographic dye injection, stents, cardiac catheterization, balloon angioplasty and other types of recanalizing of atherosclerotic arteries, etc. because the closure device 18 is designed to cause immediate hemostasis of the tissue and blood vessel of the patient. It is contemplated that the sealing assembly 16 of the present invention may be used with nearly any catheterization or other medical procedure wherein it is desirable to seal an incision or puncture to prevent the loss of the patient's body fluid therethrough, including laparoscopic or similar procedures. Additionally, the closure device 18 of the present invention may be used with nearly any catheterization or

other medical procedure or introduction device wherein it is desirable to reliably locate the lumen of a blood vessel, duct or target organ of a patient's body to prevent the loss of the patient's body fluid therethrough, including laparoscopic, cardioscopic, endoscopic, intracardiac or similar procedures.

Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 16 a combination of components forming the sealing assembly, a portion of which includes various non-bioabsorbable devices for deploying the bioabsorbable closure device 18 to seal a percutaneous puncture tract 14. The puncture tract 14 includes not only the opening in the wall of the vessel but also the passageway in the tissue located between the vessel and the skin surface 12 of the patient which is formed when the procedure is performed.

As used herein, the distal end of an element is referred to as the end of the element nearest to the patient and the proximal end of an element is referred to as the element furthest from the patient.

In order to more fully understand and appreciate the present invention, a brief description of a conventional angiographic catheterization procedure through the femoral artery of the patient is set forth herein. In such a procedure, an angiographic needle (not shown) is inserted percutaneously through the epidermal and dermal layer of the skin 12 of the patient at a preferred angle of approximately 25 to 45 degrees. The needle is inserted between about 6 mm and 70 mm percutaneously into the skin of the patient until the needle pierces the femoral artery. The puncture of the artery 10 by the needle is then confirmed by the physician and a small diameter guide wire (not shown) is inserted through the needle for a distance of approximately 15 to 20 cm. The needle is then withdrawn over the guidewire while pressure is applied to the artery 10 to limit the bleeding and prevent the formation of a

hematoma at the puncture site. A dilator (not shown) and an outer introducer or catheter procedure sheath are inserted over the guidewire and the guidewire is then removed from the inside of the dilator. Next, the catheter is advanced through the procedure sheath to the final desired location and the procedure is performed. Once the procedure has been completed, the catheter is removed and only the procedure sheath remains in the puncture to allow the user to perform a sheath exchange or insert the procedure sheath of the present invention into the puncture over a guide wire or using another conventional procedure to insert the sealing assembly 16. Therefore, the procedure sheath which is used to perform the initial procedure may be the same as or different from the access sheath 20 which forms part of the sealing assembly 16 as described hereinafter

As shown in Figures 1-11, a preferred form of the present invention consists of the sealing assembly 16 which generally includes the access or procedure sheath 20, the closure device 18 and related components such as the push rod 36, extension rod 34 and bypass member 42 as described below. As shown in the drawings, the closure device 18 of the present invention includes a generally elongate and preferably cylindrical rod-shaped member 22 which is constructed of a porous, biodegradable material such as a polymerized polylactic acid, or polyglycolic acid matrix or similar bioabsorbable materials may also be used. The distal end 24 of the rod member includes the anchor member 26 as described in further detail below. The present invention also preferably includes a tubular collagen member 28 which surrounds a portion of the rod member 22 proximally of the anchor member 26 and a retainment ring 30 which is located proximally thereof as also described below. Additionally, one or more of the bioabsorbable rod member 22, collagen member 28 and retainment ring 30 of the closure device 18 may be formulated to include a conventional clotting agent, such as a tissue

thromboplastin, which is incorporated in at least a portion of the desired material to accelerate local hemostasis and which will allow the physician to maintain the patient on an anticlotting agent such as heparin after the procedure has been performed. It is further anticipated that at least a portion of the closure device 18 may be formulated to include a radiopaque material therein to allow the placement of the closure device 18 to be observed using conventional visualization methods. The use of radiopaque materials also allows the physician to identify the location of the closure device at a later time if a further procedure is necessary.

The closure device 18 preferably has three basic bioabsorbable components; namely, a rod member 22 with a preferably integral or substantially integral intraarterial anchor member 26, a tubular collagen member 28 and a retainment ring 30. The proximal end of the rod member 22 is preferably threadedly or otherwise releasably connected to an elongate extension rod 34. The extension rod 34 forms part of the initial sealing assembly that is inserted through the access sheath 20. Alternately, the push rod 36 may be included as part of the initial sealing assembly although the push rod 36 is preferably used once the access sheath 20 is removed from the puncture tract 14 as described below. The extension rod 34 is a relatively small diameter member which extends through the access sheath 20 to enable the user to manipulate the closure device 18 while it is in the access sheath 20. The push rod 36 is a larger diameter member which encircles the extension rod 34 and is used to push the retainment ring 30 distally along the rod member 22 as described in more detail below. Both the extension rod 34 and push rod 36 are removed after the closure device 18 is positioned in the puncture tract 14 and may therefore be constructed of conventional catheter type materials such a PVC or similar polymeric materials.

The rod member 22 is in the form of a preferably molded and generally elongated cylindrical-shaped member; e.g., a hemostatic and resorbable material such as a lactide and glycolide polymer or similar material which may further include a hemostasis promoting and/or radiopaque material in at least a portion thereof. In one form of the rod member 22, a lip member 23 may be positioned proximally of the anchor member 26 to provide resistance to the passage of the collagen member 28 thereover. The length and diameter of the rod member 22 is chosen to facilitate the insertion of the closure device 18 into and through the puncture tract 14 for the prompt sealing of the puncture tract 14 and wall of the blood vessel.

The anchor member 26 is preferably an elongated, relatively stiff, low-profile, resorbable member which is arranged to be seated inside the artery against the artery wall generally adjacent to or contiguous with the puncture 11. The anchor member 26 is preferably molded as part of the distal end 24 of the rod member 22 and is preferably made of a non-hemostatic resorbable polymer which is similar to or compatible with the resorbable rod member 22.

The collagen member 28 is preferably shaped as an elongate tubular member which is formed of a non-allergenic hemostatic resorbable material such as a collagen sponge or foam material. The retainment ring 30 is preferably a relatively small member which is slidably positioned along the rod member 22 proximally of the collagen member 28 and is preferably formed of a molded resorbable polymeric material such as a lactide/glactide copolymer. The outer diameter of the retainment ring 30 is preferably greater than the outer diameter of the extension rod 34 to enable the push rod 36 to move the retainment ring 30 distally along the rod member 22 as described below. A reinforcing suture 32 or other material may be molded into the distal end portion 24 of the rod member 22 to reinforce and connect the anchor member 26 to the rod member 22. The interconnection between the anchor member 26 and the rod

member 22 serves to provide a pivot point for the relative movement of the anchor member 26. This interconnection is preferably formed to enable the movement of the anchor member 26 from an insertion position wherein the anchor member 26 is aligned with the lengthwise dimension of the rod member 22 and a laterally oriented position wherein the anchor member 26 extends laterally from the distal end 24 of the rod member 22 to engage the wall of the blood vessel of the patient. The collagen member 28 is slidably positioned along the rod member 22 so that distal movement of the push rod 36 and retainment ring 30 along the rod member 22 causes compression of the collagen member 28 as well as radial expansion and distal movement of the collagen member 28 along the rod member 22. Moreover, as will be appreciated from the description to follow, the entire closure device 18 is designed to reduce post-procedure puncture complications, provide secure puncture sealing, enable faster patient ambulation, cause minimal inflammatory reaction and resorb completely within a relatively short period of time; e.g., sixty to ninety days.

In accordance with the following general description of the method of use of the closure device 18 of the present invention, the closure device 18 is used after the interventional procedure is finished. In accordance with the method of this invention, the access sheath 20 is exchanged with the procedure sheath using conventional catheter exchange procedures or is left in the artery and the procedure sheath is used as the access sheath 20. The location of the distal end of the access sheath 20 is then confirmed as being within the blood vessel and extending slightly beyond the puncture tract 14. The closure device 18 is either previously inserted into the access sheath 20 or is next inserted into the access sheath 20 so that the extension rod 34 extends from the proximal end of the access sheath 20. The closure device 18 is then moved distally in the access sheath and partially deployed

(ejected) from the distal end of the access sheath 20 by moving the extension rod 34 distally with respect to the access sheath 20 while holding the access sheath 20 fixed relative to the skin surface 12 of the patient. On further distal movement of the extension rod 34 relative to the access sheath 20, the anchor member 26 and a portion of the rod member 22 are passed out of the distal end of the access sheath 20 and deployed into the artery lumen. As the anchor member 26 passes from the distal end of the access sheath 20, the orientation of the anchor member 26 is changed with respect to the lengthwise dimension of the rod member 22 as the proximal end of the anchor member 26 passes beyond the distal end of the access sheath. The anchor member 26 pivots to extend laterally from the distal end 24 of the rod member 22 as a result of the anchor member's preferred bias towards the lateral orientation.

The closure device 18 is then withdrawn with respect to the access sheath 20 by withdrawing the extension rod 34 until resistance is felt. The resistance is caused when the anchor member 26 catches on the distal end of the access sheath 20. Once this occurs (and assuming that the anchor member 26 is in the correct orientation when it catches on the end of the access sheath 20), the access sheath 20 and the extension rod 34 are then withdrawn together a short distance relative to the skin 12 of the patient. This withdrawal or proximal movement with respect to the puncture causes the anchor member 26 to engage (catch) on the artery wall contiguous with the puncture tract 14. The access sheath 20 is then withdrawn relative to the skin of the patient and the extension rod 34. The proximal movement of the access sheath relative to the skin 12 of the patient and the closure device causes the rod member 22, collagen member 28 and the retainment ring 30 to be exposed to the tissue in the puncture tract 14.

The push rod 36 may then be positioned on the sealing assembly to surround a portion of the extension rod 34 and

rod member 22. The push rod 36 is then moved distally relative to the extension rod 34 and rod member 22 to push the retainment ring 30 distally along the rod member 22 and bring the collagen member 28 into engagement with the wall of the artery adjacent to puncture site. The distal movement of the retainment ring 30 along the rod member 22 also has the effect of deforming the collagen member 28 into a collagenous mass which preferably has a larger diameter than the diameter of the puncture in the wall of the blood vessel. This expansion in the diameter of the collagen member aids in holding the closure device 18 in place in the blood vessel and puncture without requiring a separate procedure or step to expand the puncture tract 14. As shown in the drawings, the installed closure device sandwiches the wall of the blood vessel between the anchor member 26 and the collagen member 28. Moreover, since the collagen member 28 is preferably formed of a compressed collagen, it also preferably expands in the presence of fluid or blood within the puncture tract 14 when deployed, thereby further contributing to the collagen member's 28 radial enlargement. The retainment ring 30 is moved along the rod member 22 by pushing the push rod 36 distally with respect to the extension rod 34 and rod member 22 until the retainment ring 30 encounters a locking member 38 which may be a groove or other change in the diameter or circumference on the distal portion of the rod member 22. The push rod 36, retainment ring 30 and locking member 38 serve as an immediate tamper of the collagen member 28 to provide rapid sealing and hemostasis in the puncture tract 14. Once the retainment ring 30 reaches the locking member 38, the extension rod 34 may be disconnected from the proximal end of the rod member 22 and the extension rod 34 and push rod 36 may be removed from the puncture tract 14.

The closure device 18 is now maintained in the desired position wherein the wall of the blood vessel is clamped between the collagen member 28 and the anchor member 26 by

the natural contraction of the tissue of the patient around the closure device 18, the initial clotting action of the patient and the expansion of the hemostatic collagen member 28. Thus the artery wall is sandwiched between the collagen member 28 and the anchor member 26 and the flow of fluids through the puncture tract and puncture is stopped by physical and physiological actions. Within a few hours after deployment, the anchor member 26 will be coated with fibrin and thus attached firmly to the arterial wall, thereby minimizing the possibility of distal embolization. Furthermore, the preferred use of a reinforcing suture 32 or similar member in the rod member 22 and anchor member 26 further reduces the already unlikely possibility that the anchor member 26 may somehow separate from the distal end 24 of the rod member 22.

During prior clinical testing of a similar anchor member, only a small deposit of the anchor material will remain along the wall of the blood vessel after approximately thirty days. In fact, resorption of all components of the closure device 18 is believed to occur after approximately sixty days. Thus, the resorbable anchor has an insignificant hemodynamic effect on blood flow and functions to assist in the reliable positioning of the remaining components of the closure device as described above while being completely absorbed in a relatively short period of time.

As will be appreciated by the more detailed description of the components of the present invention to follow, deployment of the preferred form of the closure device 18 using the access sheath 20 is easy, quick and reliable. Anchoring and deployment of the collagen member 28 is repeatable, safe and effective without the need for external pressure to enable more rapid ambulation of the patient. Hemostasis is believed to occur almost instantaneously; e.g., in 15 seconds or less, when the closure device 18 is deployed properly.

The collagen member 28 comprises a cylindrical and tubular member formed of a preferably compressible, resorbable, collagen foam, such as that sold by Colla-Tec, Inc. of Plainsboro, New Jersey. The collagen member 28 is arranged to be compressed from a larger diameter configuration to a smaller diameter, elongated configuration which is positioned along the rod member 22 proximally of the anchor member 26 and inserted into the access sheath 20. In the configuration wherein the collagen member 28 is compressed and inserted into the access sheath 20, the additional diameter of the collagen member 28 along the rod member 22 is very small and, therefore, suitable for disposition within the access sheath 20. The length of the collagen member 28 is preferably sufficient to seal a substantial portion of the lengthwise dimension of the puncture proximally of the wall of the blood vessel and is also sufficient to prevent puncture tract bleeding which results from capillary bleeding in the puncture tract.

The anchor member 26 basically comprises a thin, narrow strip or bar of resorbable material such as a resorbable lactide/glycolide polymer sold by Medisorb Technologies International L.P. under the trade designation MEDISORB. The strip is sufficiently rigid such that once it is in position with the artery it is resistant to deformation to preclude it from bending to pass back through the puncture tract 14 through which it was first introduced. The anchor member 26 preferably has a generally planar top surface, a generally planar bottom surface and a centrally located surface which is pivotally connected the distal end 24 of the rod member 22. Each end of the anchor member 26 is preferably rounded. The centrally located surface of the anchor member 26 preferably includes a hemispherical projection which is located at the center of the top surface. The hemispherical projection preferably includes one or more reinforcing sutures 32 extending therethrough and a

longitudinally extending slot disposed perpendicularly to the top surface of the anchor member 26 having the sutures molded therein. The overall shape of the anchor member 26 is chosen so as to allow the anchor member 26 to initially pass through the wall of the blood vessel and into the blood vessel while preventing the retraction therethrough and without significantly obstructing the flow of blood through the blood vessel. In this regard the biased and laterally extending connection between the anchor member 26 and the rod member 22 is preferably effected during the molding of the rod member 22 and anchor member 26 and is preferably further reinforced by the use of the relatively stiff suture 32.

The details of the preferred form of the access sheath 20 will now be described. As can be seen, the access sheath 20 basically comprises a conventional catheter introducer which includes an elongated tube 40 formed of a somewhat flexible material, such as polyethylene or polyvinyl chloride, so that the closure device 18 may be freely passed through the access sheath 20 into an operative position within the patient's artery, notwithstanding any curvature of the elongated tube 40 which may exist.

In accordance with a preferred embodiment of this invention, the outside diameter of the access sheath 20 is approximately 8-French because the majority of relevant procedures utilize an 8 french procedure sheath. It should be understood that the choice of an 8 french access sheath is for illustration purposes in describing the preferred form of the present invention and it is contemplated that other sizes are readily within the scope of the present invention. The proximal end of the access sheath 20 may include a rigid funnel shaped bypass member 42 inserted or mounted thereon to enable the closure device 18 and extension rod 34 to be inserted through a conventional hemostasis valve (not shown) which is formed on the distal portion of the access sheath 20. The distal end of the

elongated tube 40 preferably necks down into a conventional tapered configuration and may include a longitudinally extending slot 44 thereon to facilitate the pivoting of the anchor member 26 and to indicate the desired alignment of the anchor member 26 relative to the distal end of the access sheath 20 as described below.

As shown in the drawings, the extension rod 34, bypass member 42 and push rod 36 of the present invention include various markings and projections thereon to provide the user with visual and tactile indications of when certain steps in the insertion of the closure device 18 have been accomplished. As described above, the extension rod 34 is an elongate member which is releasably attached to the proximal end of the rod member 22. The length of the extension rod 34 is chosen so that when the anchor member 26 of the closure device 18 extends beyond the distal end of the access sheath 20, the finger grip area 46 on the proximal end of the extension rod 34 will extend proximally of the proximal end of the access sheath 20. Additionally, a pair of circumferential bands 48 are located on the extension rod 34 distally of the finger grip area 46. The proximal circumferential band is used to signal to the user that the anchor member 26 of the closure device 18 is extended beyond the distal end of the access sheath 20 when the proximal circumferential band 48 reaches the bypass member 40 that is positioned in the proximal end of the access sheath 20. The extension rod 34 also includes a further circumferential colored band 50 located distally of the pair of circumferential bands 48 on the proximal portion of the extension rod 34 to signal to the user when the retainment ring 30 has reached the locking member 38 on the rod member 22. Finally, the bypass member 42 preferably includes the slot or alignment markings 44 thereon which may be aligned with the slot 52 on the distal end of the access sheath to allow the user to readily align the anchor member 26 with the slot 52 on the distal end of the access sheath 20 by aligning the anchor member 26 with

the slot or markings 44 on the bypass member 42 as the closure device is inserted into the proximal end of the access sheath 20. The bypass member 42 may also include a further reference detent (not shown) in its periphery located diametrically opposite to the desired position of the anchor member 26 to serve as a visual guide to help the user orient the closure device 18 to a proper yaw angle with respect to the central longitudinal axis of the closure device 18 for insertion within the access sheath 20 as will be described later.

In the preferred method of use of the present invention, the closure device 18 is inserted through the distal end of the access sheath 20 prior to deployment. In particular, the anchor member 26 is passed through the bypass member 42 prior to use to temporarily change the orientation of the anchor member 26 from lateral to longitudinal with respect to the lengthwise dimension of the rod member 22. Therefore, during the initial insertion of the closure device 18 into the tract and puncture, the anchor member 26 is disposed longitudinally within the elongated tube portion 40 of the access sheath 20. The collagen member 28 is located within the elongated tube portion 40 of the access sheath 20 proximally of the longitudinally oriented anchor member 26. Additionally, the distal end 24 of the rod member 22 preferably overlies the proximal end of the anchor member 26 so that the overall diameter of the distal end 24 of the rod member 22 and the longitudinally disposed anchor member 26 is approximately equal to the diameter of the rod member 22 proximally thereof and less than the diameter of the portion of the rod member 22 having the collagen member disposed therearound.

As can be seen in Figure 2, the access sheath 20 preferably includes a conventional luer fitting side port on the proximal end thereof. The bypass member 42 is preferably a funnel shaped member which is sized to extend into the opening in the luer fitting and is secured in

place therein by any suitable means, including frictional contact, to maintain the hemostatic valve on the proximal end of the access sheath 20 open during the procedure.

The positioning of the access sheath 20 in the artery may be accomplished utilizing an artery locator device or an obturator which identify the location of the artery wall by the flow of blood or by physical contact with the wall of the blood vessel. Alternately, and significantly less preferable, the depth of the puncture may be physically measured and then the access sheath 20 may be moved to the appropriate measured depth in the puncture using various markings on the access sheath and/or by using selected access sheaths having specified lengths. After the access sheath 20 is positioned in the artery, a stopcock may be opened to observe the flow of blood therefrom (thereby indicating that the inlet port or window is within the artery). The access sheath 20 is then retracted (moved proximally) until the blood flow through the stopcock just stops, thereby indicating that the distal end of the access sheath has just left the artery lumen. The access sheath 20 is then reinserted approximately 10 mm into the puncture to ensure that the distal end of the access sheath 20 is at the desired position within the artery. Blood flow should be reestablished through the stopcock at this time to verify that the elongated tube 40 is not kinked or otherwise obstructed. Then the stopcock is closed. From this point on, the access sheath 20 must be kept fixed with respect to the skin 12 of the patient to ensure that the access sheath 20 does not move distally or proximally in the puncture tract 14. The bypass tube 42 is then inserted into the proximal end of the access sheath 20 to open the hemostatic valve. The closure device is then inserted into and aligned with the bypass member 42 to cause the anchor member 26 to be deflected from the laterally extending position to the longitudinal position. The closure device 18 is then moved distally past the bypass member 42 and into the access sheath 20.

The slot or markings 44 on the bypass tube 42 are identified by the user and the bypass tube 42 is grasped by the user and oriented so that the slot or markings face up and away from the patient. This alignment ensures that the anchor member 26 is located towards the patient. The rigid nature of the bypass tube 42 facilitates the passage of the closure device 18 through the hemostasis valve and also orients the anchor member 26 longitudinally with respect to the rod member 22 to protect the closure device 18 from damage. The closure device 18 and extension rod 34 are then pushed fully down the access sheath 20 so that proximal circumferential band 48 on the extension rod 34 is aligned with the bypass member 42 on the proximal end of the access sheath 20 to indicate to the user that the distal end of the closure device 18 is aligned with the end of the access sheath and the anchor member 26 is located in the artery 10 and extends beyond the distal end of the access sheath 20.

The sealing assembly 16 is then operated to determine if the anchor member 26 has been properly deployed. To that end the access sheath 20 is continued to be held by the user to prevent axial and rotational movement, and the closure device 18 is carefully withdrawn with respect to the access sheath 20 and the skin 12 of the patient. This action causes the anchor member 26 to engage or catch onto the distal end of the access sheath 20. As the anchor member 26 catches on the distal end of the access sheath 20, resistance will be felt by the user. This resistance must be noted by the time the distal circumferential band 48 on the extension rod 34 is visible along the bypass member 42. If resistance is felt, then the anchor member 26 will have caught on the distal end of the access sheath 20 at the location of the hemispherical projection on the anchor member 26. If resistance is not felt, the anchor member 26 has not deployed and the above insertion sequence must be repeated by turning the closure

device 18 about its axis by one-quarter turns to either side before it is again withdrawn.

If the resistance is felt before the distal circumferential band 48 is visible above the bypass member 42, this will indicate that only one of the ends of the anchor member 26 has caught on the end of the access sheath 20, an undesired occurrence. Accordingly, the closure device 18 must be reinserted within the access sheath 20 and the foregoing procedure retried, this time by turning the closure device 18 about its axis by one-quarter turns to either side before it is again withdrawn relative to the access sheath 20.

Once the anchor member 26 has been properly deployed to the laterally extending orientation (Figure 5), the access sheath 20 and the closure device 18 are held together and withdrawn as a unit from the puncture, whilst swinging the unit toward the vertical. This action causes the anchor 26 to engage or catch onto the inner surface of the artery 10 contiguous with the puncture tract 14. The access sheath 20 is then removed. Inasmuch as the anchor member 26 is trapped against the interior of the artery wall, the removal of the access sheath 20 causes the rod member 22 and the collagen member 28 to be exposed to the fluids and blood present in the puncture tract 14. As the access sheath 20 comes out of the puncture tract, continuous steady resistance must be felt on the rod member to ensure that the anchor member 26 is properly deployed.

At this point the anchor member 26 has been deployed along the wall of the blood vessel 10 and the collagen member 28 is positioned in the puncture tract 14 proximally of the wall of the artery. At this time, the push rod 36 is installed over the extension rod and the collagen member 28 is moved distally in the puncture tract 14 by the distal movement of the push rod 36. In particular, the user compacts the collagen member 28 by gently moving the push rod 36 distally to cause the retainment ring 30 to move distally along the rod member 22. The push rod 36 and

retainment ring 30 are manually slid down the rod member 22 by the user so that the retainment ring 30 is moved distally in the puncture tract 14 until the retainment ring 30 engages the locking member 38 as indicated to the user by the colored band 50 reaching the proximal end of the push rod 36. This movement of the retainment member 30 moves the collagen member 28 distally to the desired location in the puncture tract 14. A gentle distal movement is adequate to achieve the desired result; i.e., to assist the distal end portion of the collagen member 28 to conform to the outside of the blood vessel contiguous with the puncture and to assist to lock the collagen member 28 and anchor member 26 in place until hemostasis occurs (which happens very quickly, thereby further locking the closure device in place). It should be noted that during the distal movement of the retainment ring 30 and collagen member 28, care must be taken to maintain tension on the rod member 22 at a load greater than that used on the push rod 36 to ensure that the action doesn't propel the collagen member 28 into the interior of the blood vessel.

After the retainment ring 30 reaches and is engaged by the locking ring 38, the extension rod 34 may be rotated or otherwise manipulated relative to the rod member 22 to separate the extension rod 34 from the rod member 22. Alternately, the length of the rod member 22 may be chosen so that the proximal portion of the rod member 22 extends beyond the skin level of the patient and the rod member 22 may then be cut to separate the rod member 22 from the extension rod 34. The extension rod 34 and push rod 36 are then removed and any portion of the rod member 22 extending above the retainment ring 30 may be excised. The closure device 18 is then preferably left in this condition without being disturbed for a few minutes to allow complete hemostasis. After that time the condition of the patient may be evaluated and the patient may be ambulated or discharged as determined by the physician.

With the closure device 18 in the final sealing position, the anchor member 26 (the only portion of the closure device within the blood vessel) does not take up a substantial portion of the interior of the blood vessel and, thus, does not block off or otherwise impede the flow of blood therethrough. Since the components of the closure device 18 are all formed of resorbable materials, the closure device 18 can be left in place within the body until it is absorbed.

As shown in Figures 14 and 15, the retainment ring of the present invention may be formed of various shapes. In this embodiment, the alternate form of the retainment ring 60 preferably includes a circular base section 62 with an opening 64 for the rod member 22 to pass therethrough and a pair of leg members 66 which are biased to press against the rod member 22 as the retainment ring is moved distally therealong. As shown in Figure 15, the leg members 66 preferably assist in expanding the proximal portion of the collagen member 28 to provide yet another mechanism to securely retain the sealing device in the puncture tract.

As should also be appreciated from the foregoing, the closure device of the present invention, the instrument for deploying it and the method of use enables the ready, effective and efficient sealing of a percutaneous puncture in an blood vessel. The closure device 18 may allow for the continuance of anticoagulation post-procedure, more aggressive use of thrombolytic agents and safer use of large bore catheters. It should also reduce discomfort and complication rates for patients, allow many in-patient procedures to be performed safely on an out-patient basis, decrease the time and cost of interventional procedures and reduce exposure of hospital personnel to human blood.

While the preferred forms of the present invention are described and illustrated herein, it will be obvious to those skilled in the art that various changes and modifications may be made thereto without departing from

the scope of the present invention as defined by the following claims. For example, it is anticipated that various modifications may be made to the anchor member and access sheath to facilitate the deployment and retention of the closure device in the desired position in the puncture.

BIOABSORBABLE HEMOSTATIC SEALING ASSEMBLY

CLAIMS

What is claimed is:

1. An assembly for sealing an incision or puncture in the body of a patient wherein the incision or puncture extends through the tissue of the patient into a blood vessel, duct or lumen of the patient, the assembly comprising;

an anchor member formed of a first bioabsorbable material and sized to be positioned in the blood vessel, duct or lumen of the patient;

an elongate member formed of said first bioabsorbable material;

a compressible member formed of a bioabsorbable material and said compressible member being slidably positioned along said elongate member and said compressible member cooperatively sealing the incision or puncture from the flow of fluids therethrough in combination with said first member.

2. The assembly of claim 1 wherein said elongate member is a rod-shaped member and said first bioabsorbable material of said elongate member further includes a hemostasis promoting material therein which is absorbable within the body of the patient.

3. The assembly of claim 1 further including a ring member slidably positioned along said elongate member.

4. The assembly of claim 3 wherein said elongate member includes distal and proximal end portions thereon and said ring member is movable along said elongate member to contact and slide said compressible member distally

along said elongate member and said ring member frictionally engages at least a portion of said elongate member.

5. The assembly of claim 3 wherein said ring member is formed of said first bioabsorbable material.

6. The assembly of claim 3 wherein said ring member is formed of a rigid material.

7. The assembly of claim 3 wherein said ring member at least partially encircles a portion of said elongate member.

8. The assembly of claim 3 wherein said ring member is positioned proximally of said compressible member.

9. The assembly of claim 1 wherein said compressible member is a tubular collagen member which is inserted into the incision or puncture along said elongate member.

10. The assembly of claim 1 wherein said anchor member is sized to be operatively positioned in the blood vessel of a patient and said elongate member is sized to be operatively positioned in the incision or puncture and said compressible member extends along said elongate member such that said anchor member, said elongate member and said compressible member cooperatively seal the incision or puncture from the flow of blood from the blood vessel therethrough.

11. The assembly of claim 10 wherein said anchor member is sized to be positioned along the inner surface of the wall of the blood vessel of the patient and said compressible is sized to be positioned along the outer surface of the wall of the blood vessel and said elongate member is sized to be positioned therebetween.

12. An assembly for sealing a puncture in the body of a patient wherein the puncture extends from the skin of the patient, through the wall of a blood vessel and into the blood vessel of the patient, the assembly including a closure device comprising;

a first member formed of a bioabsorbable material and said first member is sized to be positioned in the blood vessel of the patient generally adjacent to the puncture;

a second member formed of a bioabsorbable material and said second member is sized to extend proximally from said first member and through at least a portion of the puncture; and

a third member formed of a bioabsorbable material and said third member is a tubular member which is slidable along said second member and is sized to extend along the outer surface of the wall of the blood vessel of the patient to cooperatively seal the puncture from the flow blood therethrough.

13. The closure device of claim 12 wherein said first member and said second members are formed of a generally rigid bioabsorbable material.

14. The closure device of claim 12 wherein said third member is a compressible collagen member which is slidable distally along said elongate member to a location adjacent to the outer wall of the blood vessel.

15. The assembly of claim 12 including an access sheath having a proximal end portion with a bypass member therein to enable said closure device to pass therethrough.

16. The assembly of claim 12 including an access sheath and wherein said second member includes a longitudinal axis and said first member is oriented

generally parallel to said longitudinal axis when said closure device is in said access sheath and is generally perpendicular thereto upon being expelled from said access sheath.

17. The assembly of claim 16 wherein said first member is formed to be biased towards being oriented generally perpendicular to said longitudinal axis of said second member.

18. The assembly of claim 12 including an access sheath having a proximal end portion with a generally funnel-shaped bypass member therein to enable said closure device to pass therethrough.

19. A method of sealing a puncture formed in the body of a patient wherein the puncture extends generally from the skin of the patient, through the wall of the blood vessel and into a blood vessel of the patient, the method comprising:

inserting a sealing assembly having an access sheath and a bioabsorbable sealing device into the previously formed puncture and the blood vessel of the patient;

pushing the closure device through the access sheath and into the puncture and blood vessel such that the distal end portion of the closure device is in the blood vessel;

allowing the distal end portion of the closure device to extend laterally from the remainder of the closure device;

withdrawing the laterally extended distal end portion of the closure device from the blood vessel until the locating member contacts a predetermined portion of the inner wall of the blood vessel;

pushing a push rod along the proximal end portion of the closure device to move a retaining ring into a

locking ring on the closure device to seal the puncture from the flow of blood therethrough.

20. The method of claim 19 further including the step of moving the retaining ring in the puncture to cause the distal movement of a bioabsorbable member along the closure device to a location generally adjacent to the wall of the blood vessel.

21. The method of claim 19 further including the step pushing the push rod along the proximal end portion of the closure device until an indicator on the push rod reaches a predetermined location associated with the access sheath to indicate that the retainment ring has reached the desired location along the closure device.

22. The method of claim 19 further including the step of moving a tubular collagen member along the closure device in response to the movement of the retainment ring along the closure device to cause the wall of the blood vessel of the patient to be sandwiched between the collagen member and the distal end portion of the closure device.

23. The method of claim 19 further including the step of the closure device into the access sheath until a marker associated with the closure device reaches a predetermined location on the access sheath to signal to the user that the distal end portion of the closure device is extending beyond the distal end portion of the access sheath.

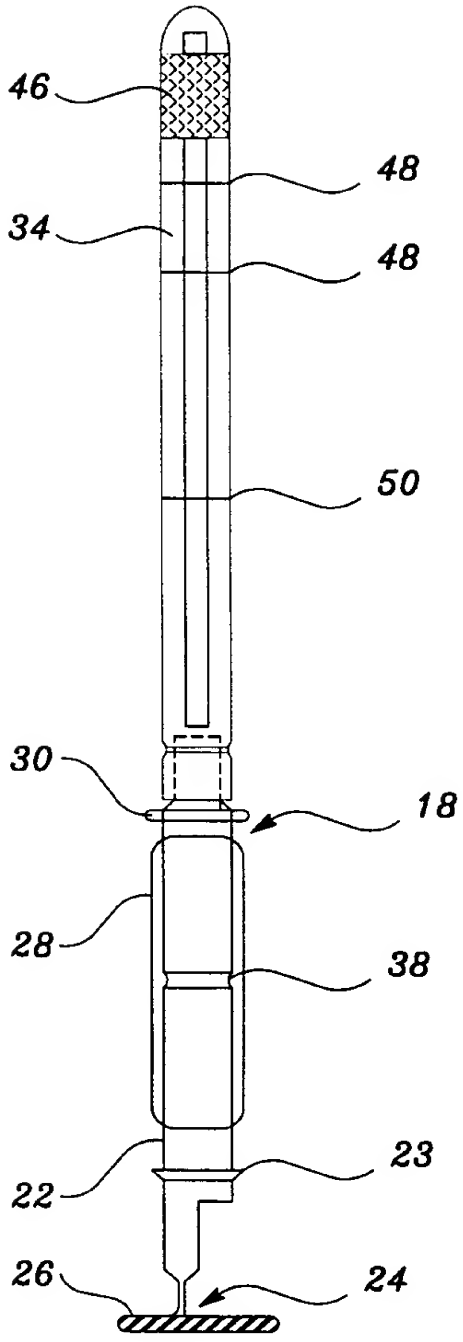

figure 1

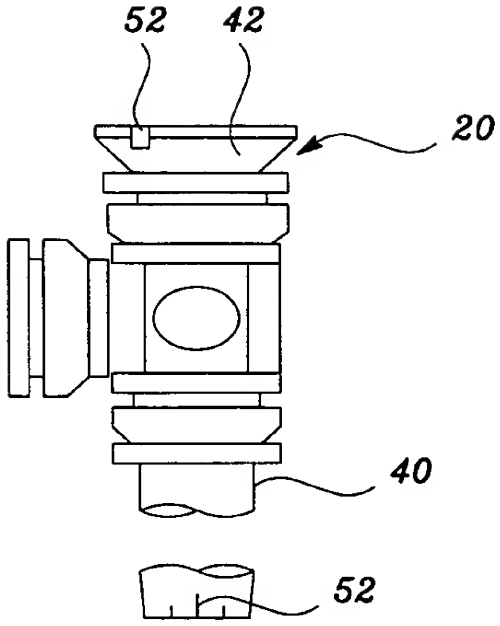

figure 2

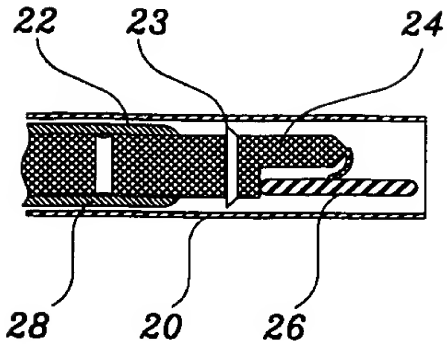

figure 4

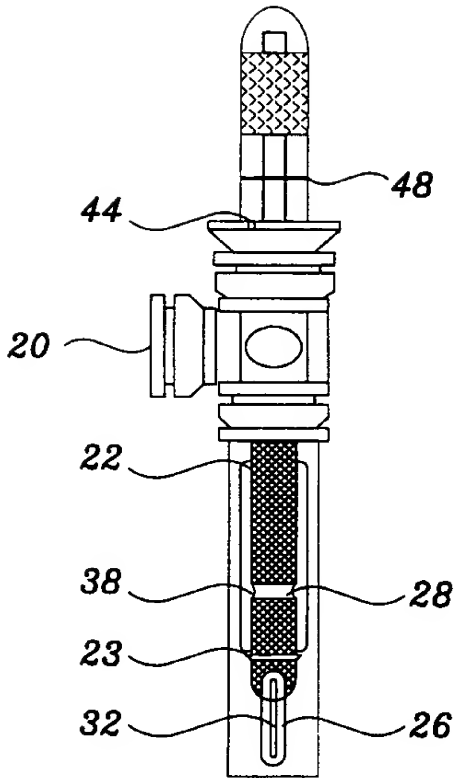

figure 3

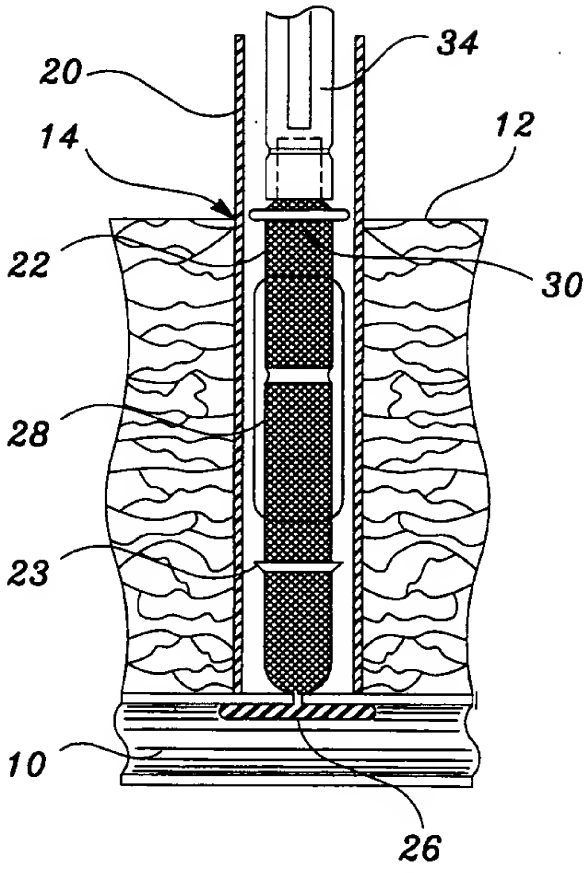

figure 6

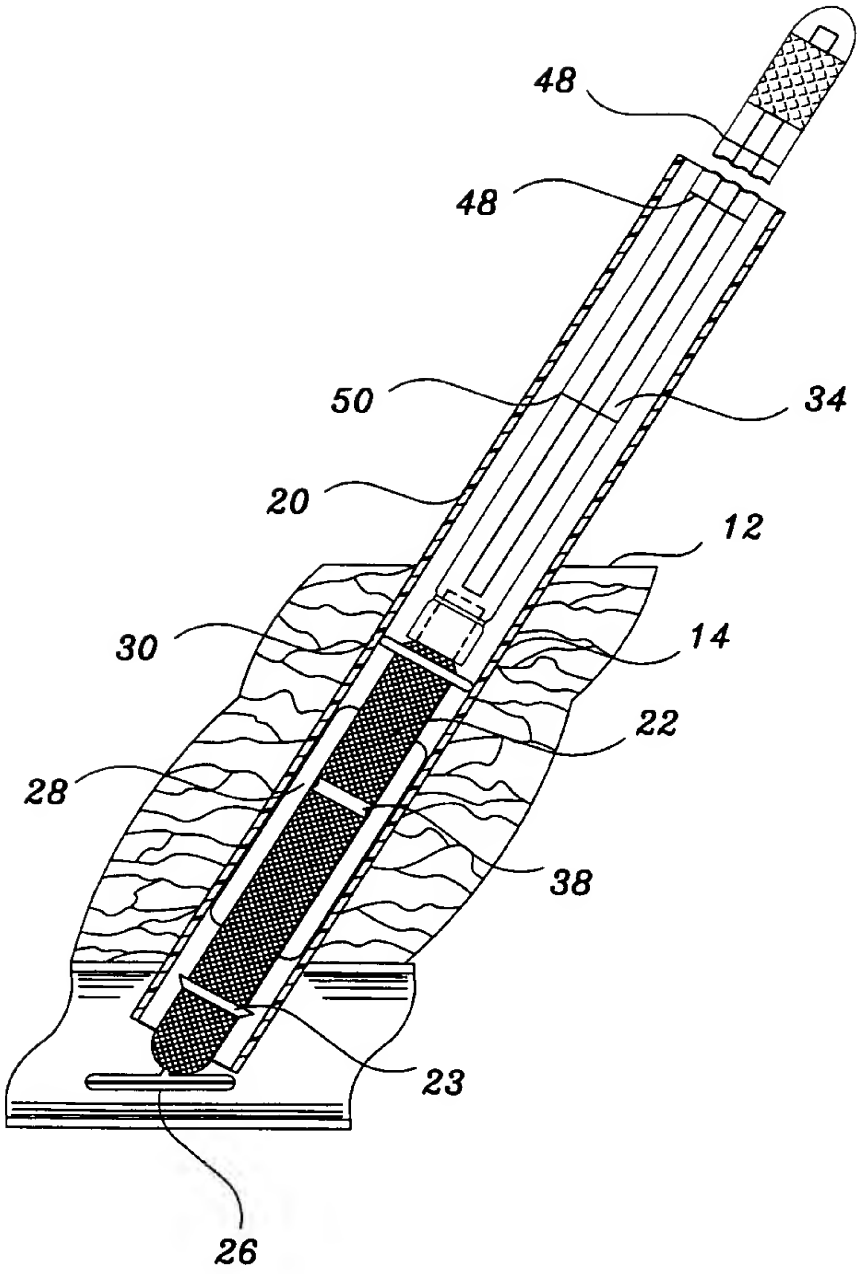

figure 5

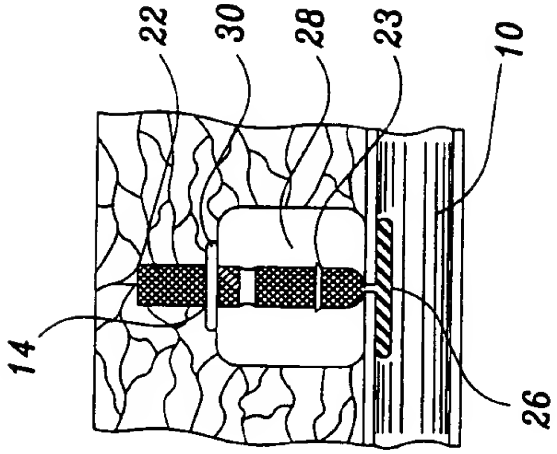

figure 10

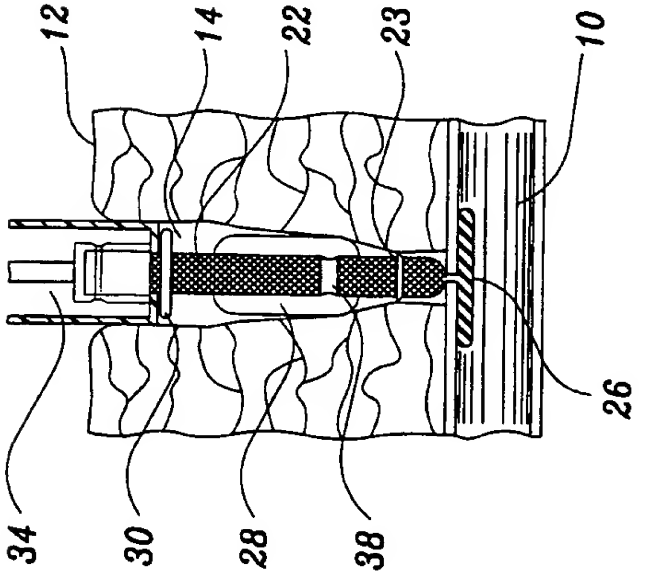

figure 7

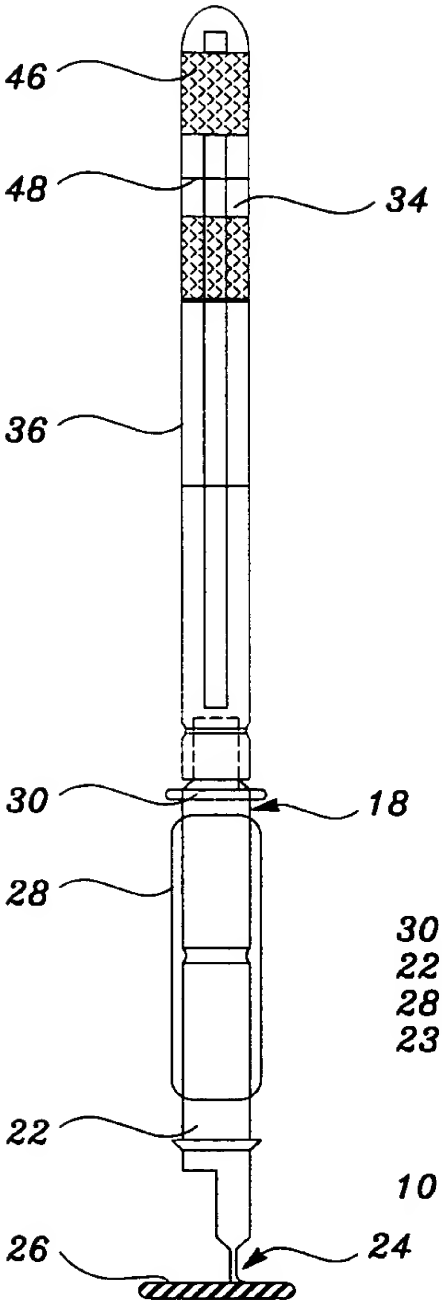

figure 8

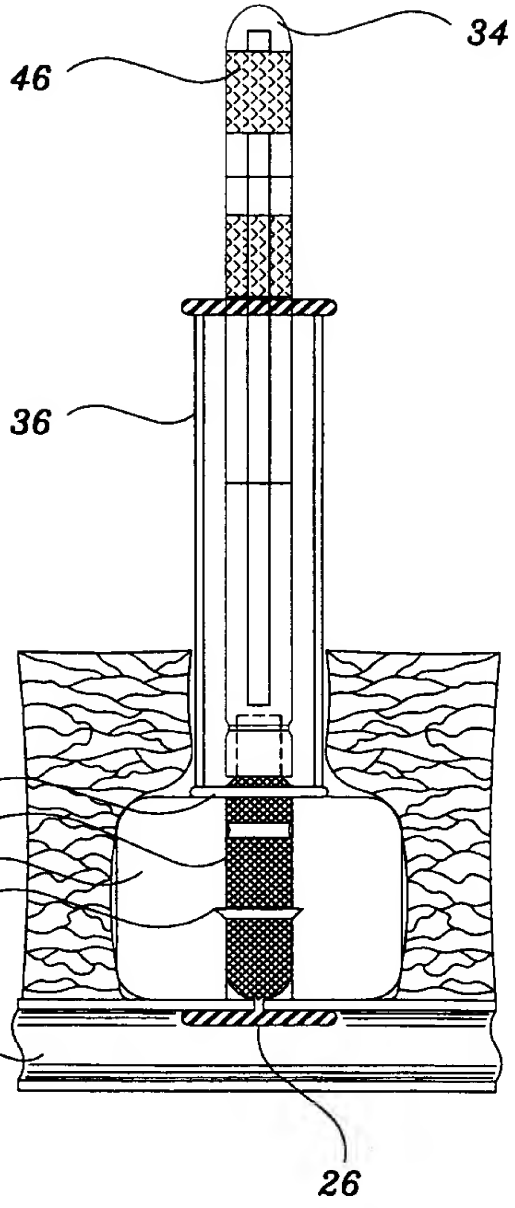

figure 9

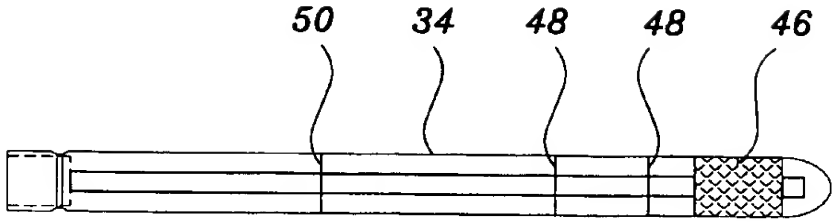

figure 11

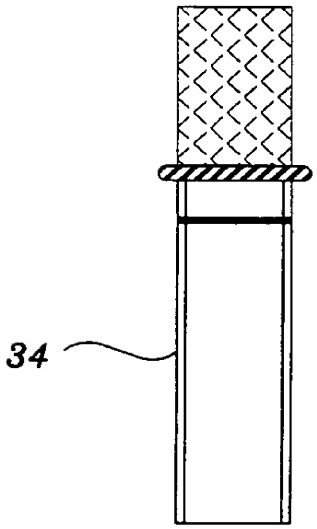

figure 12

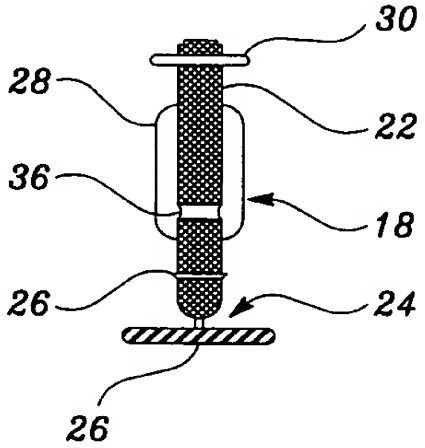

figure 13

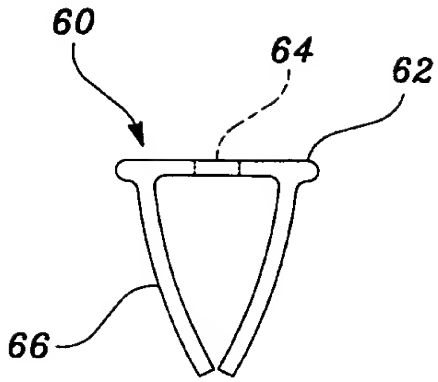

figure 14A

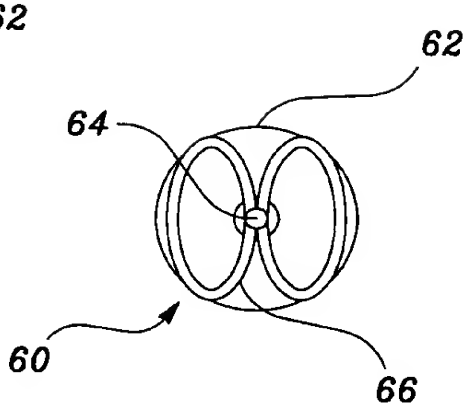

figure 14C

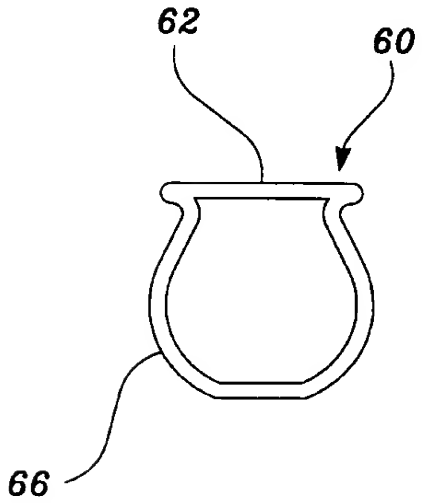

figure 14B

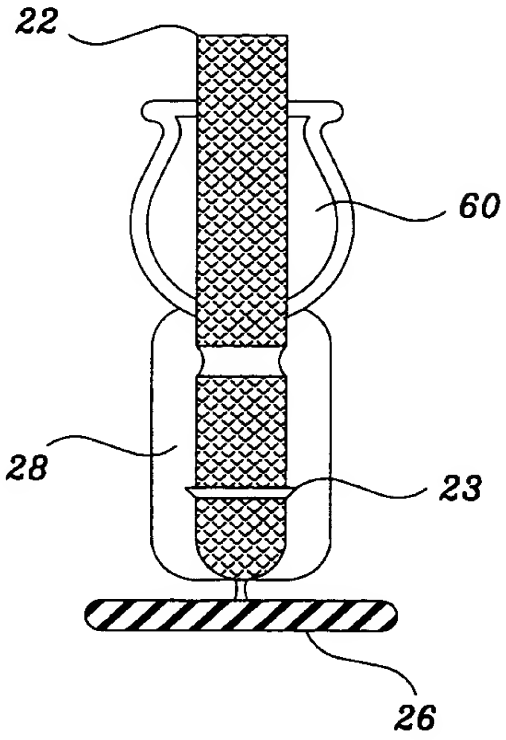

figure 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01189

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 17/04
US CL :604/15; 606/213
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 604/15, 60; 606/213, 215

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,531,759 A (KENSEY et al) 02 July 1996, col. 5 lines 31-64.	1-23
A	US 5,437,631 A (JANZEN) 01 August 1995, col. 2 lines 48-69, and col. 3 lines 1-43.	1-23
A	US 5,496,332 A (SIERRA et al) 05 March 1996, col. 4 lines 26-67.	1-23

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 15 APRIL 1998	Date of mailing of the international search report 05 MAY 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GARY JACKSON Telephone No. (703) 308-4302

Form PCT/ISA/210 (second sheet)(July 1992)*